

Supplemental Table 1: Criteria for experiencing an adverse event as a result of AVA: systemic reactions. Subjects were at least 18 years of age or older and had received the anthrax vaccine and experienced on at least 1 occasion, in temporal association with the vaccination; new onset symptoms that did not exist chronically or recurrently prior to the first dose of anthrax vaccine nor had another non-vaccine related etiology been identified by laboratory or other diagnostic testing. Reduction in functional capacity that interfered with activities of daily living, work productivity, sleep, and/or leisure activity resulted in the subject using or considering the use of some analgesic therapy for relief of symptoms.

Type of systemic reaction	Clinical presentation or notes	Optional criteria (may or may not be present)	Qualifier	Inclusion
Persistent/prolonged Myalgia and or Arthralgias Syndrome (PMAS)	I. Prolonged myalgias described as migratory muscle pains, aching, soreness or heaviness; or II. Variable symptoms of arthralgias described as soreness, aching, pain within and/or around the joints with no evidence of frank arthritis by physical examination	I. Myalgias/arthralgias last longer than 30 days with pain level= \geq 3/10 on visual-analogue (VAS) scale; II. Myalgias/arthralgias recur with equal or greater severity with next exposure to same vaccine(s); III. Myalgia/arthralgia pain not adequately controlled with moderate to low dose analgesics (non-narcotic); may include use of at least one of the following: a. Ibuprofen 400-600 mg 3-4 times/day b. Acetaminophen 650 mg every 4-6 hours c. Aspirin two tablets every 4-6 hours IV. May describe and/or demonstrate	Number of doses received	One (1) or more
			Onset of symptoms after vaccination	0-45 days
			Duration of symptoms	\geq 72 hours
			Pain level (on the visual and/or numeric analogue scale 0-10)	>3
			Percent (%) reduction in function (percentage scale of 0-100%, 100%=bedridden)	\geq 25% reduction

		intermittent muscle fasciculations and/or spasms		
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Type of systemic reaction	Clinical presentation or notes	Optional criteria (may or may not be present)	Qualifier	Inclusion
Headaches (HA): New and/or exacerbation	<p>I. HA-new: new onset post-immunization headache (clinical presentation includes two (2) or more of the following criteria:</p> <ul style="list-style-type: none"> a. Worsening and/or reproducible with \geq vaccinations b. Quality of headache: different qualities/severity compared to any prior headache experience c. Frequency of headaches in excess of any prior headache experience <p>II. HA-exacerbation: headache with all criteria listed above but a past history of headaches interfering with work and/or leisure activity. Exacerbation includes an increase in intensity and/or frequency of</p>	None	Number of doses received	One (1) or more
			Onset of symptoms after vaccination	0-48 hours
			Duration of symptoms	≥ 72 hours
			Pain level (on the visual and/or numeric analogue scale 0-10)	>3
			Percent (%) reduction in function (percentage scale of 0-100%, 100%=bedridden)	$\geq 25\%$ reduction

	headaches in temporal association with an anthrax vaccine immunization.			
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Type of systemic reaction	Clinical presentation or notes	Optional criteria (may or may not be present)	Qualifier	Inclusion
Fatigue: New	A new symptom of fatigue (or a synonym) that is the primary complaint and is not relieved by rest and interferes with an individual's function. Clinical presentation includes at least one of the following specified new symptoms: I. Post-exertion/exercise malaise/fatigue worsening for >24 hours II. Impaired memory or concentration; severe enough to cause substantial reduction in previous levels of occupational, educational, social, or personal activities is a case defining symptom of chronic fatigue syndrome and is a common accompaniment in many fatigue states	None	Number of doses received	One (1) or more
			Onset of symptoms after vaccination	0-45 days
			Duration of symptoms	> 72 hours
			Severity level (on the visual and/or numeric analogue scale 0-10. 10= bedridden)	>3
			Percent (%) Reduction in function (Percentage scale of 0 - 100%, 100%= bedridden)	≥25% reduction

	<p>III. Unrefreshing sleep IV. Sore throat variably with tender cervical or axillary lymph nodes V. Muscle pains VI. Multi-joint pains VII. Symptoms not adequately controlled with self-medication VIII. Symptoms adversely impact sleep (no prior sleep disorder) IX. Reproducible &/or worsening of symptoms with > 2 doses</p>			
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Supplemental Table 2: Criteria for experiencing an adverse event as a result of AVA: large local reactions. Subjects were 18 years of age or older and had experienced at least one severe large local reaction at the vaccination site in temporal association with the Anthrax Vaccine.

Type of systemic reaction	Clinical presentation or notes	Qualifier	Inclusion
Large local reaction	Large local reactions following anthrax vaccination may occur in a reproducible fashion, worsening in severity (if more than one dose was received). Clinical Presentation may include: I. Neurological symptoms in the affected limb may include variable duration and severity of numbness, tingling, burning, weakness, pain and/or loss of coordination II. Local reactions may include the development of a subcutaneous nodule that is variably tender and may be associated with persistent pain syndromes III. Severe large local reactions can be mistaken for cellulites	Number of doses received	One (1) or more
		Onset of symptoms after vaccination	1 hour - 1 week
		Duration of symptoms	≥48 hours
		Pain level (on the visual and/or numeric analogue scale 0-10)	>3
		Severity of symptoms	I. ≥4 inches (>100 mm/10 cm or larger than the base of a soda can)(A diameter limit of 2 inches is described in the vaccine product insert as an expected local reaction size II. Involving the upper arm III. Extending below the elbow